

REMARKS

Claims 1-23 were pending in the application. The Examiner has rejected claims 1-23 under 35 U.S.C. §112 second paragraph as being indefinite. The Examiner has also rejected claims 1-23 under 35 U.S.C. §103(a) as being obvious over GB 1,299,557 ("*Lek*") in view of "Lecture Notes, Chemistry CM3101 - Natura Products Chemistry, Dept. of Chem./School of Pharm., Univ. of College Cork ("*Keating*"). Applicants have canceled claim 1 without prejudice and amended claims 2-3, 5, 9-10, 12, 17 and 21-23.

Claim 2 has been made independent by incorporating all of the limitations of claim 1. Claim 2 has also been amended to recite that the concentration of ethanol in the mixture is about 5-30% (v/v). Support for the amendment is found in the specification at, e.g., page 2, paragraph [0011]. Claims 3 and 22-23 have been amended similarly. Claims 5, 9-10 and 12 have been amended to correct grammatical or editorial errors, and claims 2, 4, 6, 14, 15, 22 and 23 have been amended to change "extracting" to "extraction" as suggested by the Examiner. Claim 21 has been amended to make the language clearer. Claims 17 and 23 have been amended to have proper antecedent basis.

35 U.S.C. § 112, Second Paragraph

Claims 1-23 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the recitation of "extracting". Applicants respectfully disagree with the Examiner's rejection. Firstly, the term "extract" (and therefore "extracting") is a commonly used term in the art. As an illustration, both *Lek* and *Keating*, cited by the Examiner in the Office Action, use the term in describing processes for production of ergot alkaloid. (See

e.g., *Lek*, first page, lines 52-55; and *Keating*, page 9, Line 4 under "General aspects"). Secondly, the term is widely used in the specification. Therefore, a person skilled in the art would be able to ascertain the meaning of the term based on its common usage as well as the specification. However, since the Examiner indicates that "extraction" would be acceptable, and since applicants submit that there is no real difference between these two terms, the claims have been amended to accept the Examiner's suggestion. It is therefore clear that this rejection is no longer applicable.

Therefore, the rejected claims are not indefinite, and applicants respectfully request withdrawal of the rejection.

35 U.S.C. §103

Claims 1-23 have been rejected under 35 U.S.C. § 103(a) as being obvious over *Lek* in view of *Keating*. The Examiner alleges that *Lek* teaches a process for isolating ergot alkaloids by extracting ergot with toluene, filtering through alumina then dissolving the product in ethanol. The Examiner alleges that the toluene-ethanol solution is then partially evaporated to crystallize the ergot alkaloid from solution and that petroleum ether was added to aid in crystallization. The Examiner further alleges that *Keating* teaches that solvents such as toluene and ethanol can be used to extract ergot alkaloids and that subsequent acid-base extraction methods can be employed.

Lek does not teach or suggest using a mixture of toluene and ethanol for the purpose of isolating an ergot alkaloid from ergot. To the contrary, *Lek* teaches the use of a water-immiscible solvent, such as chloroform, benzene, trichloroethylene, toluene,

methylene chloride, or dichloroethane, for the isolation of ergot alkaloids (see, *Lek*, first page, lines 40-55). Once the alkaloids are adsorbed on alumina, ethanol is only then disclosed for use in eluting the alkaloids from the water-immiscible solvent. It is here that this patentee mentions the use of "a more polar solvent or a mixture of the above-mentioned solvents with methanol or ethanol." (*Lek*, first page, lines 61-69.) Again, this is done only after both the extraction and filtering steps. Accordingly, *Lek* does not teach method of "extracting ergot with a mixture comprising toluene and ethanol to form a primary extract." (instant application, claim 1, (emphasis added)).

Likewise, Keating also utterly fails to teach or suggest using a mixture of toluene and ethanol to isolate an ergot alkaloid from ergot. *Keating* lists the solvents that may be used for extracting ergot on page 9. While toluene is on this list, no mention is made of using ethanol in the extraction, nor is there even any mention of using a combination of any solvents for such extraction.

Thus, neither *Lek* nor *Keating* teaches or suggests using ethanol for isolating an ergot alkaloid from ergot. In addition, since ethanol is not a water-immiscible solvent, *Lek* appears to teach away from using ethanol in the primary ergot extraction process. Thus, a person skilled in the art would not have been led by *Lek* and *Keating* to the presently claimed process. As neither *Lek* nor *Keating*, nor the combination of the two, teaches extracting ergot with a mixture comprising toluene and ethanol to form a primary extract, Applicants respectfully submit that the Examiner has not established a *prima facie* case of obviousness in view of the cited prior art. Of course, the cancellation of claim 1, and

the amendments to claim 2 now make it absolutely clear that the references in no way teach or suggest the invention thereof. Accordingly, Applicants request withdrawal of this rejection.

Claims 1-23 have also been rejected under 35 U.S.C. § 103(a) as being obvious over *Cvak*. The Examiner alleges that *Cvak* teaches a process of isolating an ergot alkaloid by extracting ergot with a mixture of toluene and ethanol to form a primary extract and transferring the ergot from the primary extract by further extraction with an aqueous acidic solution, namely HCl. The Examiner acknowledges that *Cvak* does not teach crystallization of the extracted ergot alkaloids.

Cvak does refer to the use of various organic solvents for the extraction of ergot. This reference thus mentions "methylenedichloride, trichloroethylene, ethyl acetate, acetone, methylisobutyl ketone and mixtures of toluene with methanol or ethanol and ether with ethanol. . . ." (*Cvak*, page 375, lines 16-18.) This reference, however, does not teach or suggest the concentrations of ethanol and/or toluene in such a mixture. Indeed, there is no reference to any concentrations in any two-component systems therein. The present inventors have discovered that a mixture which contains about 5-30% of ethanol offers both high efficiency and selectivity. (See instant application at ¶ [0011]). *Cvak* does not teach or suggest that the ethanol content would have any effect on the extraction process. Accordingly, a person skilled in the art would not have been led by *Cvak* to the claimed process. Withdrawal of this rejection is therefore respectfully requested.

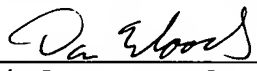
As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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